510(k) Summary

JUN 1 2 2013

1. Submitter's Identification:

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Attn: Lakshman Agadi, President

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Attn: Stephanie Blair, Attorney

Date Summary Prepared: June 10, 2013

2. Name of Device:

Device Name:
AL-106, AL-106SA and AL-106B MedGyn Digital Video Colposcope

Trade/ Proprietary Name:
AL-106, AL-106SA and AL-106B MedGyn Digital Video Colposcope

Common Name:
Colposcope

Classification:

21 CFR884.1630	Colposcope	85HEX	Class II

3. Predicate Device Information

Identification of Legally Marketed Device with Which We Claim Substantial Equivalence (Predicate Device):

The Goldway Digital Video Colposcope Imaging System, model number SLC-2000, manufactured by Goldway, 510(k) number: K021153.

Note that the Goldway Digital Video Colposcope Imaging System included an LCD screen for viewing the images from the colposcope, but the MedGyn Digital Video Colposcope does not include a monitor.

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4. Device Description

a. Executive Summary:

The MedGyn Digital Video Colposcope, models AL-106, AL-106SA and AL-106B (collectively, the "MedGyn Colposcope"), has the same application as traditional colposcopes. However, while traditional optical colposcopes use binocular eyepieces for magnification, the MedGyn Colposcope uses electronic imaging technology to assist doctors in reviewing, checking, analyzing, and diagnosing abnormalities or lesions of the vulva, vagina, cervix and external genitalia. It is designed to be used in hospitals, doctors' offices and clinics by qualified or trained personnel.

The MedGyn Colposcope is an active, non-contact examination device. It uses a HAD CCD color digital video camera with a digital magnification of up to 40x (or only 32x for model AL-106B), a field of view of 52° at 1x and 2° at 32X, and a green filtered light source. The camera is attached to a floor stand; model AL-106SA has a swing-arm floor stand. A cable coming from the bottom of the floor stand connects to the signal conversion box. The customer then uses the composite video cable or the s-video cable to connect a commercially available monitor to the conversion signal box.

Tissue is magnified and viewed on the doctor's own computer monitor (not included with device). Both the doctor and the patient can observe the image on the monitor's screen, thus helping the doctor explain the abnormalities and the suggested treatments to the patient, and allowing patient to see the abnormalities for herself and better understand her medical situation.

b. Technical Description:

The MedGyn Colposcope has the following technical features:

- 1/4" HAD CCD digital video camera
- Fast auto focus, and manual focus
- Digital Magnification 1~40x (For AL-106B model, digital magnification is 1~32x)
- Optical Magnification 1~36x (For AL-106B model, optical magnification is 1~18x)
- Double circular LED group light source
- 3 grade green filter function
- S-video output
- Image freeze control
- Field of View (at a working distance of 200mm)
    - At 1X >= 195mm (52°)
    - At 32X >= 6.978mm (2°)
- Depth of view: 5mm~120mm
- Magnification and acetic acid reaction timing display
- Multi-function button control which allows for direct and convenient control of operations such as magnification, zoom, focus, freeze and green filter.

5. Intended Use:

MedGyn's Digital Video Colposcope is intended for magnified viewing of the tissues of the vagina, cervix and external genitalia in order to assist doctors in diagnosing abnormalities such as lesions or cancer, and selecting areas for biopsy. The images from the Digital Video

Colposcope are to be viewed on a color monitor. The Digital Video Colposcope is intended for use in hospitals, clinics, and doctors' offices.

6. Comparison to Predicate Device:

Both the predicate device, the Goldway SLC-2000 Digital Video Colposcope Imaging System, and the MedGyn Colposcope have the same intended use, which is to provide an imaging system that facilitates direct viewing and imaging of the tissues of the vagina, cervix and external genitalia.

The MedGyn Colposcope is very similar to the predicate device, with only slight differences in the CCD chip, resolution, illumination, focal length, depth of view and field of view. The MedGyn Colposcope allows for a wider direction of view and a higher optical magnification than Goldway's colposcope. Both colposcopes use LED light and a green filter, and are configured to provide the necessary working distance and magnification for patient observation.

The Goldway and MedGyn devices are both self-contained, stand-alone units incorporating light, power and video into a compact system. Both devices are offered with similar floor stands, but MedGyn also offers a swing-arm stand (model AL-106SA). However, note that the Goldway Digital Video Colposcope Imaging System included an LCD screen for viewing the images from the colposcope, but the MedGyn Digital Video Colposcope does not include a monitor.

7. Discussion of Non-Clinical Tests Performed:

The following voluntary Performance Standards were met:

- IEC60601-1:1988 + A1:1001 + A2: 1995 (MEDICAL ELECTRICAL EQUIPMENT PART1: GENERAL REQUIREMENTS FOR SAFETY)
- IEC60601-1-1:2000 (MEDICAL ELECTRICAL EQUIPMENT - PART 1-1: GENERAL REQUIREMENTS FOR SAFETY - COLLATERAL STANDARD: SAFETY REQUIREMENTS FOR MEDICAL ELECTRICAL SYSTEMS)
- IEC60601-1-2:2007 (MEDICAL ELECTRICAL EQUIPMENT PART1-2: GENERAL REQUIREMENTS FOR SAFETY –COLLATERAL STANDARD: ELECTROMAGNETIC COMPATIBILITY-REQUIREMENTS AND TESTS)
- ISO 8600-3:1997 (MEDICAL ENDOSCOPES AND ENDOSCOPIC ACCESSORIES -- PART 3: DETERMINATION OF FIELD OF VIEW AND DIRECTION OF VIEW OF ENDOSCOPES WITH OPTICS)
- ISO 8600-5:2005 (MEDICAL ENDOSCOPES AND ENDOTHERAPY DEVICES -- PART 5: DETERMINATION OF OPTICAL RESOLUTION OF RIGID ENDOSCOPES WITH OPTICS)

Resolution Information:
MedGyn's Digital Video Colposcopes have the following resolution:

- On-Axis Resolution: 11.31 line-pairs/mm
- On-Axis Angular Resolution: 0.02534 degrees

Distortion Information (note - a geometrical distortion of ≤ 3% is acceptable):

- AL-106B = +1%
- AL-106 & AL-106SA = +2.49%

Thermal Safety Testing Information:

- After working continuously for 30 minutes, from a distance of 200mm, the temperature of the test surface rose by only 0.2^{O} Celsius.

8. Discussion of Clinical Tests Performed:

Not Applicable.

9. Conclusion

The MedGyn Colposcope has equivalent indications for use and principals of operation as compared to the predicate device. The differing features of the MedGyn Colposcope do not affect the use, safety or effectiveness of the device. Therefore, the MedGyn Colposcope is substantially equivalent to the Goldway Digital Video Colposcope Imaging System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 12, 2013

MedGyn Products, Inc.
% Ms. Stephanie Blair
Attorney
Intellectual Property Law Group, LLP
12 South First Street, 12th Floor
SAN JOSE CA 95113

Re: K122973
Trade/Device Name: AL-106, AL-106SA, AL-106B MedGyn Digital Video Colposcope
Regulation Number: 21 CFR§ 884.1630
Regulation Name: Colposcope
Regulatory Class: II
Product Code: HEX
Dated: May 23, 2013
Received: May 29, 2013

Dear Ms. Blair:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.
You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122973

Device Name: AL-106, AL-106SA, AL-106B MedGyn Digital Video Colposcope

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MedGyn's Digital Video Colposcope is intended for magnified viewing of the tissues of the vagina, cervix and external genitalia in order to assist doctors in diagnosing abnormalities such as lesions or cancer, and selecting areas for biopsy. The images from the Digital Video Colposcope are to be viewed on a color monitor. The Digital Video Colposcope is intended for use in hospitals, clinics, and doctor's offices.

Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K122973